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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,166

Applicant(s)

KOKUBO ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment and Remarks filed on October 29, 2004 has been entered. Claims 1-8, 10-12 14-15 are pending. Any rejection made under 35 USC 112, 2nd paragraph that is not addressed in this Office Action is considered obviated in view of the amendments. Applicant's arguments with respect to the art rejections have been fully considered but are not found persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-2, 4-5, 7-8, 13-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gray US Patent 5,885,547.

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant's central argument is on the basis that it would not have been obvious to make the microspheres of Gray in a spherical shape. (see Remarks at page 5, 4th para-page 6, 2nd para.)

3. With respect to the product claims 1-7 and 15, Applicant alleges that unlike the instantly claimed products, "...microspheres of Gray may be turned by the blood flow and end up moving somewhere to open capillary because of their irregular shapes." Applicant then makes a conclusionary statement that Gray's microspheres are not capable of embolizing in the capillary... " (see Remarks at page 6, 2-3rd para.).

4. In response Examiner states that Applicant argues unclaimed limitations. Accordingly, the arguments are not commensurate with the scope of the claims.

Further, such line of arguments is not persuasive because Applicant has not provided any evidence to prove the conclusion.

Assuming that the instant pending claims are directed to a specific “embolizing function” as Applicant argues, the claims would still stand rejected. The instant claims 1-7 and 15 are product claims. A recitation of the intended use or a function provided by the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Moreover, Applicant has not provided any evidence that Gray’s microspheres are not capable of performing such function. Thus, Applicant statements are not persuasive.

5. Applicant then argues that Gray teaches against using solid glass microspheres. (see Remarks at page 6, 5th para.). Applicant relies on col 3, lines 15-16 of Gray’s patent, where Gray states “these glass microspheres have several disadvantages.” *Id.*

6. In response, Examiner that Gray’s teachings are not a direct teaching away from the instant claims. Thus, Applicant’s conclusion is not correct. Here, Applicant appears to misinterpret what it means to “teach away” from a patented invention. “In general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the results sought by the applicant.” *In re Gurley*, 31 USPQ2d 1130, 1131-2 (Fed. Cir. 1994). Here, the mere fact that there is an alternative means of improving yttria containing micropsheres, as described by

Gray, does not preclude obvious optimization of the physical characteristics of Gray's microsphere.

Specifically, the portions of Gray's patent that Applicant characterizes as a "teaching against" (col 3, lines 8-22) does not discourage one of ordinary skill in the art to optimize the physical characteristics of Gray's microspheres. Gray at col 3, lines 8-22 describes what have traditionally been the shortcomings of yttrium polymeric or glass microspheres; namely unpredictable leaching of radioactivity, higher specific gravity and impurities. (see Gray's patent at col 3, lines 1-20). Such statement is hardly a teaching away within the meaning reasoned in *Gurley*.

In fact, Gray specifically encourages modifications of physical characteristics of yttrium-90 microspheres by asserting that "majority of patients benefit from treatment with radioactive microspheres with appropriate physical characteristics." (see Gray at col 3, lines 48-51). Thus, one of ordinary skill in the art would have most likely performed further experimentation to determine what other physical characteristics of Gray microspheres are capable of producing the same results described in Gray.

Second, Applicant has not provided any evidence or explains how the disclosures of the prior art show that the instantly claimed invention is unlikely to be productive of Gray's desired result, when Gray in fact introduces the concept of making stable yttrium-90 containing ceramic microspheres. Simply, there is no statement in Gray showing that the instantly claimed physical characteristics would have been a less attractive possibility for delivering radioactive yttrium. Therefore, Examiner concludes that a person of one ordinary skill, upon reading the Gray's reference, would not have

been discouraged from optimizing the path set out by Gray, or would have taken a direction divergent from the path that was taken by the applicant.

7. Finally, Applicant's reliance on *In re Gordon*, 221 USPQ 1125 (Fed Cir. 1984) or *In re Ratti*, 123 USPQ 349 (CCPA 1959) is misplaced. On both cases, the rejections of record attempted to modify the art in a manner that the prior art apparatus could not have otherwise functioned. For example, in *Gorden* the cited prior art apparatus relied on gravity to operate; however, the Examiner applied the art in a manner that it had to function in an upside down orientation which would have rendered to apparatus inoperable. (see *Gordon* at 1127). The Court then reasoned that there was no desirability in the art to use the prior art in a manner that it would render inoperable for its intended purpose. *Id.*

This is not the case here. There is no teaching in the Gray or the art; at the time the invention was filed, to discourage the use of Gray's microspheres in a manner claimed here. In fact, the state of art as described in Day expressly suggests the use of spherical microspheres to deliver radioactive yttria. In fact, the Declaration provided by Mr. Inoue shows the production of spherical microspheres by Gray's method (see Inoue's Declaration, the SEM photograph of Experiment B microspheres). Thus, since Gray clearly teaches the products of the instant claims, modifying its shapes would have been achieved by routine experimentation.

8. With respect to the method claims, claims 8, 10-12, 14, Applicant argues that there is a difference between the process of Gray and the instant method. However,

Examiner responds that it is not clear what this difference is in the language of the claim?

9. Applicant argues that unlike in Gray, the ultimate product produced by the instant method is uniformly spherical. (see Remarks at page 7, last para). In response,

Examiner states this argument is not commensurate with the scope of the claims.

10. Examiner points out that the instant claims are not directed to any percentages of spherical microspheres produced by the claimed method. All that is required by the pending claims is to produce a radioactive microsphere. Therefore, Applicant's arguments are not commensurate with the scope of the claims.

11. Further the pending claims do not provide any additional functional step that is not described by Gray. In fact, Gray meets all elemental steps of the instant method claims. Gray process produces radioactive microspheres having not less than 99% by weight of a crystal of an oxide of yttrium, employs a thermal plasma (thermal jet) to melt the spray dried oxide, and further irradiates its yttrium aggregates with neutron beams to produce radioactive microspheres (col 5, line 34-45, 50-55; col 6, lines 25-40). Gray only differs to specifically state that his microspheres are in the shape of a sphere or that his microspheres contain 47% by weight of radioactive yttrium. However, such features are viewed to be optimizable.

12. The Declaration filed by Mr. Inoue has been entered and considered but does not overcome the rejection because it refers only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope

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with the claims. See MPEP § 716. Applicant attempts to establish the instant methods achieve a production of uniform spheres at a higher rate than does Gray. However, the scope of the instant claims neither exclude nor further limit the process steps envisioned by Gray. In fact, the SEM photograph of Experiment B microspheres (the Gray's method) in the Declaration establishes production of radioactive microspheres in spherical shape.

Thus, the rejection is maintained

13. Claims 1-5, 8, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray US Patent 5,885,547 in view of Day US Patent 5,302,369.

14. Applicant has not provided any additional arguments with respect to this rejection. Therefore, the rejection is maintained for the reasons of record

15. Claims 1-8, 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray US Patent 5,885,547 in view of Day US Patent 5,302,369 and further in view of Huang US Patent 5,073,404.

16. Applicant has not provided any additional arguments with respect to this rejection. Therefore, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112

17. Claims 8, 10-12, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. The term "high frequency induction thermal plasma" in claim 8 is a relative term which renders the claim indefinite. The term "high frequency" is not defined by the

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claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

19. The language of claim 8 and the metes and bounds of the claim are not clear. Specifically, what are the first step, second step and the third step of the instant claim 8? Line 2 of the claim states: the method comprising preparing a microsphere having not less than 99% by weight of a crystal of an oxide of yttrium....” However, line 3 of the claim further states that such preparing step is “through melting of an oxide powder containing yttrium as starting material by passing the starting material through a high frequency induction thermal plasma...” These recitations link various functional outcomes without clearly pointing out what are the active method steps for which Applicant is seeking protection? Applicant is encouraged to clarify the active method steps by positively and clearly reciting the step of the instant method claim.

Conclusion

20. The attached PTO-892 is provided to reflect that Huang reference has been considered.

21. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

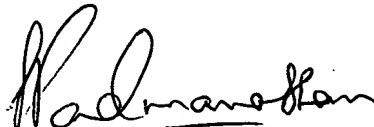
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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